Method for operating gaming devices

Publication number: AU761822 (B2)
Publication date: 2003-06-12
Inventor(s): ACRES JOHN F
Applicant(s): ACRES GAMING INC
Classification:
- international: ***G07F17/32;*** **G07F17/32;** (IPC1-7): A63F9/22; A63F13/12
- European: G07F17/32D
Application number: AU19990024974 19990428
Priority number(s): US19980083302P 19980428; US19980134285 19980814

Also published as:

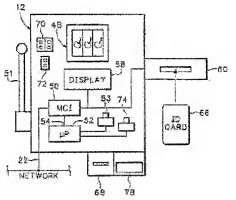
- AU761822 (C)
- US6607441 (B1)
- CA2270029 (A1)
- CA2270029 (C)
- AU2497499 (A)

Cited documents:

- AU3382299 (A)
- US5559312 (A)

Abstract not available for AU 761822 (B2)
Abstract of corresponding document: **US 6607441 (B1)**

A method for transferring credits between gaming devices connected by a network to a host computer comprising. A player account accessible by the host computer is created. The player can access the account by inserting a card into a card reader at one of the gaming devices. A credit is applied by the player to the gaming device, typically by inserting bills into a bill acceptor. The credit and any awards resulting from gaming-device play are stored on a credit meter associated with the gaming device. Access to the account is terminated when the player withdraws the card from the card reader. A player initiates a request to redeem the balance stored on the credit meter by depressing a cash-out button.; The balance on the credit meter is transferred to the player account if the cash-out button is pressed before the card is withdrawn, and is paid to the player via the gaming machine if the button is pressed after the card is withdrawn.



(12) PATENT
(19) AUSTRALIAN PATENT OFFICE

(11) Application No. AU 199924974 B2
(10) Patent No. 761822

(54) Title
Method for operating gaming devices

(51)[6] International Patent Classification(s)
A63F 009/22 A63F 013/12

(21) Application No: 199924974 (22) Application Date: 1999.04.28

(30) Priority Data

(31) Number	(32) Date	(33) Country
60/083302	1998.04.28	US
09/134285	1998.08.14	US

(43) Publication Date : 1999.11.04
(43) Publication Journal Date : 1999.11.04
(44) Accepted Journal Date : 2003.06.12

(71) Applicant(s)
Acres Gaming, Inc.

(72) Inventor(s)
John F. Acres

(74) Agent/Attorney
WRAY and ASSOCIATES,Level 4,The Quadrant,1 William Street,PERTH WA 6000

(56) Related Art
AU 33822/99
US 5559312

METHOD FOR TRANSFERRING CREDIT FROM ONE GAMING MACHINE TO ANOTHER

ABSTRACT

A method for transferring credits between gaming devices connected by a network to a host computer comprising. A player account accessible by the host computer is created. The player can access the account by inserting a card into a card reader at one of the gaming devices. A credit is applied by the player to the gaming device, typically by inserting bills into a bill acceptor. The credit and any awards resulting from gaming-device play are stored on a credit meter associated with the gaming device. Access to the account is terminated when the player withdraws the card from the card reader. A player initiates a request to redeem the balance stored on the credit meter by depressing a cash-out button. The balance on the credit meter is transferred to the player account if the cash-out button is pressed before the card is withdrawn, and is paid to the player via the gaming machine if the button is pressed after the card is withdrawn.

AUSTRALIA

Patents Act 1990

ORIGINAL

COMPLETE SPECIFICATION

STANDARD PATENT

Name of Applicant: Acres Gaming, Inc.

Actual Inventor John F. Acres

Address for service is: WRAY & ASSOCIATES
239 Adelaide Terrace
Perth, WA 6000

Attorney code: WR

Invention Title: "Method for Operating Gaming Devices"

The following statement is a full description of this invention, including the best method of performing it known to me:-

METHOD FOR OPERATING GAMING DEVICES

BACKGROUND OF THE INVENTION

Field of the Invention

The present invention relates to a method for operating gaming devices, also herein referred to as gaming machines. The gaming devices are interconnected by a computer network to a host computer. The present invention also relates to a method for paying credits on gaming devices interconnected by a computer network to a host computer.

Description of the Related Art

This specification refers to and describes content of US patent 5,655,961 and US patent application 08/843,411. However, neither the disclosures in that US patent and application nor the description contained herein of the content of that US patent and application are to be taken as forming part of the common general knowledge solely by virtue of the inclusion herein of the reference to and description of content of that US patent and application. Furthermore, this specification describes aspects of prior art gaming device systems. However, neither such aspects of prior art gaming device systems nor the description contained herein of such aspects of prior art gaming device systems is to be taken as forming part of the common general knowledge solely by virtue of the inclusion herein of reference to and description of such aspects of prior art gaming device systems.

There are several prior art systems implementing cashless gaming on electronic gaming devices, such as slot machines, that are connected to a host computer via a network. Such systems typically require a player to open a cashless-gaming account with the casino prior to playing. The player must appear before a casino cashier who creates a player record on the host computer, receives an initial deposit from the player, and enters the deposit as a credit in the player

account. The cashier also issues a cashless-wagering card to the player, who is now ready to begin cashless gaming.

The player selects a slot machine on the casino floor and inserts his or her card into a card reader associated with the slot machine. Each of the other slot machines also include associated card readers. Most prior art systems incorporate a security feature, such as a personal identification number (PIN), that must be satisfied before the system permits the player to draw on the credit in the account. In these prior art systems, the player enters his or her PIN on a keypad associated with the slot machine and card reader after insertion of the card. When the security feature is satisfied, the amount in the player's account appears on the display associated with the slot machine. The player may then draw on the account by initiating commands at the slot machine that transfer credits from the account to the slot machine. As the player transfers money from the account to the slot machine, the credit in the account decreases. If the player should be the recipient of a jackpot or other award at the slot machine, the conventional credit meter on the slot machine increments to add the jackpot or award to the balance on the credit meter.

When the player concludes playing, the balance is transferred from the credit meter to the player's cashless-wagering account responsive to a command initiated by the player. The player then withdraws his or her card and leaves the balance in the account for placing wagers

on one of the slot machines at a future time, which may be a few hours, a few days, or longer.

There are a number of disadvantages associated with prior art cashless wagering systems. First, they require casino personnel to receive payments from players to establish the account. Second, the system must generate and store extensive accounting records of the withdrawals and deposits for each player's account. Because players may return after long absences to wager the balance in the account, records of all transactions relating to the account must be maintained indefinitely. Third, because the casino may be holding money for long periods, security measures such as PINs and the like must be implemented. Finally, some systems that permit use of automated teller machines (ATMs) or credit cards to place money on account with the casino require transaction fees, subject the casino to electronic banking laws, and open possibilities for fraud.

It would be desirable to implement a system that would address at least some of the disadvantages associated with prior art cashless gaming systems.

Summary of the Invention

In accordance with a first aspect of the present invention, there is provided a method for operating gaming devices interconnected by a computer network to a host computer comprising:

creating a player account accessible by the host computer;

providing access to the player account responsive to a first command initiated by a player at one gaming devices;

transmitting data representing the player account over the network to a local memory associated with the one gaming device;

transferring credit from the player account to said one gaming device;

permitting gaming device play; and

cashing out from the gaming device responsive to a further command initiated by said player at said one gaming device.

Preferably, creating a player account accessible by the host computer comprises:

providing a tracking card to the player;

storing a player record on the host computer;

receiving an initial cash deposit from the player; and

crediting the deposit to the player account.

Preferably, said gaming devices are located in a casino, and creating a player account accessible by the host computer is performed at an automated card dispenser; alternatively, creating a player account accessible by the host computer is performed by an agent of the casino at a terminal connected to the network.

Preferably, said first command comprises insertion of a player tracking card into a card reader associated with said one gaming device.

Preferably, said further command comprises actuating a cash-out actuator at said one gaming device.

Preferably, actuating a cash-out actuator comprises depressing a cash-out button to redeem credit balance stored on a credit meter associated with said one gaming device.

In one embodiment of the method, said player account is an anonymous player account.

Preferably, said method further comprises:

measuring the time between each transaction on the player account; and

locking the player account when the time measured exceeds at least one established criterion.

In accordance with a second aspect of the present invention, there is provided a method for operating gaming devices interconnected by a computer network to a host computer that contains a plurality of player accounts accessible at the gaming devices, said method comprising:

transmitting data representing a player account over the network to a local memory associated with one of the gaming devices;

transferring any balance in the player account to a credit meter associated with the one gaming device responsive to a log-in command initiated by a player at said one gaming device;

storing any awards resulting from gaming device play on the credit meter;

detecting a player-initiated request to redeem the balance stored on the credit meter; and

transferring the balance on the credit meter to the player account.

Preferably, transferring the balance on the credit meter to the player account comprises transferring data from the credit meter to the player account in the local memory.

Preferably, the method of the present invention further comprises transferring the player account data from the local memory to the host computer responsive to a log-out command initiated by a player at said one gaming device.

Preferably, the method of the present invention further comprises:

detecting a log-out command initiated by a player at said one gaming device;

transferring any balance in the player account to a second credit meter associated with a second one of said gaming devices responsive to a log-in command initiated by the player at the second gaming device; and

storing any awards resulting from play on said second gaming device on the second credit meter.

Preferably, the method of the present invention further comprises:

initiating a timed count responsive to the log-out command; and

preventing transfer of the balance in the player account to the second credit meter if the timed count exceeds a predetermined maximum when the log-in command is initiated at said second gaming device.

Preferably, the method of the present invention further comprises:

detecting money paid by the player to the gaming device; and

applying the money paid to the credit meter of the gaming device.

Preferably, transferring any balance in the player account to a credit meter associated with the one gaming device responsive to a log-in command initiated by a player at said one gaming device comprises transferring the entire balance in the player account to a credit meter associated with said one gaming device responsive to a log-in command initiated by a player at said one gaming device.

In accordance with a third aspect of the present invention, there is provided a method for paying credits on gaming devices interconnected by a computer network to a host computer that contains a plurality of player accounts accessible at said gaming devices, said method comprising:

transmitting data representing a player account over the network to a local memory associated with one of the gaming devices;

transferring any balance in the player account to a credit meter associated with the one gaming device responsive to a log-in command at said one gaming device;

storing any awards resulting from gaming device play on the credit meter;

detecting a log-out command at said one gaming device; and

paying the balance on the credit meter to the player via said one gaming device.

Preferably, the method of the present invention further comprises preventing gaming device payment of the balance on the credit meter if the balance is above a predetermined maximum.

Preferably, the log-in command comprises inserting a card into a card reader associated with said one gaming device and wherein the log-out command comprises withdrawing the card.

Brief Description of the Drawings

The present invention will now be described, by way of example, with reference to the accompanying drawings, in which

FIG. 1 is a schematic diagram of an embodiment of a plurality of electronic gaming machines interconnected by a computer network to a host computer in which the method in accordance with the present invention may be implemented.

FIG 2 is a schematic diagram of an embodiment of a slot machine and associated hardware that can be used to implement the method in accordance with the present invention.

Detailed Description of the Preferred Embodiment

Turning now to FIG. 1, indicated generally at 10 is a schematic diagram illustrating electronic gaming machines (EGMs), like EGMs 12, 14, interconnected by a computer network. In the present embodiment, the EGM comprises a slot machine. Included in the network are three banks, indicated generally at 16, 18, 20, of EGMs. Each EGM is connected via a network connection, like connection 22, to a bank controller 24. In the present embodiment of the invention, each bank controller comprises a processor that facilitates data communication between the EGMs in its associated bank and the other components on the network. The bank controller also includes a CD ROM drive for transmitting digitized sound effects, such as music and the like, to a speaker 26 responsive to commands issued over the network to bank controller 24. The bank controller is also connected to an electronic sign 28 that displays information, such as jackpot amounts and the like, visible to players of machines on bank 16. Such displays are generated and changed responsive to commands issued over the network to bank controller 24. Each of the other banks 18, 20 of EGMs include associated bank controllers, speakers, and signs as shown, which operate in substantially the same manner.

Ethernet hub 30 connects each of the bank controllers associated with banks 16, 18, 20 of EGMs to a concentrator 32. Another Ethernet hub 34 connects similar bank controllers (not shown), each associated with an additional bank of EGMs (also not shown), to

concentrator 32. The concentrator functions as a data control switch to route data from each of the banks to a translator 36. The translator comprises a compatibility buffer between the concentrator and a proprietary accounting system 38. It functions to place all the data gathered from each of the bank controllers into a format compatible with accounting system 38. The present embodiment of the invention, translator 38 comprises an Intel Pentium 200 MHz Processor operating Microsoft Windows NT 4.0.

Another Ethernet hub 39 is connected to a configuration workstation 40, a player server 42, and to bonus servers 44, 46. Hub 39 facilitates data flow to or from workstation 40 and servers 42, 44, 46.

The configuration workstation 40 comprises a user interface. It comprises a personal computer including a keyboard, Intel Pentium Processor and Ethernet card.

The player server 42 comprises a microcomputer that is used to control messages that appear on displays associated with each EGM. Player server 42 includes an Intel Pentium Processor and an Ethernet card.

Bonus servers 44, 46 each comprise a microcomputer used to control bonus applications on the network. Each bonus application comprises a set of rules for awarding jackpots in excess of those established by the pay tables on each EGM. For example, some bonus awards may be made randomly, while others may be made to link to groups of EGMs operating in a progressive jackpot mode. Examples of bonuses that can be implemented on the network are disclosed in co-pending application no. 08/843,411, filed April 15, 1997 and assigned to the Assignee of the present application (the '411 application), which is incorporated herein by reference for all purposes. This co-pending application also describes in more detail features of the network, like that shown in Fig. 1, that may be used to implement the present invention. Also incorporated herein by reference for all purposes is U.S. Patent No. 5,655,961, assigned to the Assignee of the present application (the '961 patent), which also discloses bonuses that can be implemented by bonus servers 44, 46 and a network that could be used to implement the present invention.

FIG. 2 is a highly schematic representation of an electronic slot machine, which is typical of each of the machines in the network, and which incorporates network communications hardware as described hereinafter. This hardware is described in the '961 patent, and is referred to therein as a data communications node. Preferably the network communications hardware is like that disclosed in the '411 application, namely a machine communication interface (MCI) 50. MCI 50 facilitates communication between the network,

via connection 22, and microprocessor 52, which controls the operation of EGM 12. This communication occurs via a serial port 54 on the microprocessor to which MCI 50 is connected.

Included in EGM 12 are three reels, indicated generally at 48. Each reel includes a plurality of different symbols thereon. The reels spin in response to a pull on handle 51 or actuation of a spin button 53 after a wager is made.

MCI 50 may include a random access memory (RAM), which can be used as later described herein. The MCI also facilitates communication between the network and a vacuum florescent display (VFD) 58, and a card reader 60.

Before describing play according to the invention, description will first be made of typical play on a slot machine, like EGM 12. A player plays EGM 12 by placing a wager and then pulling handle 51 or depressing spin button 53. The wager may be placed by inserting a bill into a bill acceptor 68. A typical slot machine, like EGM 12, includes a coin acceptor (not shown) that may also be used by the player to make a wager. A credit meter 70 is a numeric display that indicates the total number of credits available for the player to wager. The credits are in the base denomination of the machine. For example, in a nickel slot machine, when a five dollar bill is inserted into bill acceptor 68, a credit of 100 appears on credit meter 70. To place a wager, the player depresses a coin-in button (not shown), which transfers a credit from the credit meter 70 to a coin-in meter 72. Each time the button is depressed a single credit transfers to the coin-in meter up to a maximum bet that can be placed on a single play of the machine. Alternatively, a maximum-bet button (also not shown) is provided to immediately transfer the maximum number of credits that can be wagered on a single play from the credit meter 70 to the coin-in meter 72.

When coin-in meter 72 reflects the number of credits that the player intends to wager, the player depresses spin button 53 thereby initiating a game.

The player may choose to have any jackpot won applied to credit meter 70. When the player wishes to cash out, the player depresses a cash-out button 74, which causes the credits on meter 70 to be paid in coins to the player at a hopper 78, which is part of machine 12. The machine consequently pays to the player, via hopper 78, the number of coins -- in the base denomination of the machine -- that appear on credit meter 70.

Typical slot machines, like machine 12, are limited in the total amount of coins that can be paid to the player from the hopper. Thus, when jackpots are in excess of the hopper-pay limit, the machine locks up and the jackpot is hand paid by casino personnel to the

player. After the jackpot is so paid, the casino personnel resets the machine to permit play to resume.

Card reader 60 reads a player-tracking card 66 that is issued by the casino to individual players who choose to have such a card. Card reader 60 and player-tracking card 66 are known in the art, as are player-tracking systems, examples being disclosed in the '961 patent and '411 application. Briefly summarizing such a system, a player registers with the casino prior to commencing gaming. The casino issues a unique player-tracking card to the player and opens a corresponding player account that is stored on accounting system 38 (in FIG. 1). The account includes the player's name and mailing address and perhaps other information of interest to the casino in connection with marketing efforts. Prior to playing one of the EGMs in FIG. 1, the player inserts card 66 into reader 60 thus permitting accounting system 38 to track player activity, such as amounts wagered and won and rate of play.

When the casino opens a player account, it may implement a coinless transfer feature in accordance with the present invention. When the account is so flagged by the casino, play may proceed as follows.

The player selects one of the network slot machines – in this case machine 12 – and inserts card 66 into reader 60. The player then inserts one or more bills into bill acceptor 68, which purchases a corresponding number of credits in the base denomination of the machine that are applied to and appear on credit meter 70. The player may also, of course, apply credits to the credit meter by depositing coin in the coin acceptor (not shown) that is part of machine 12. When the player inserts card 66 into reader 60, the player record that the casino created on accounting system 38 is fetched from the accounting system and loaded into memory in MCI 50. Insertion of card 66 into card reader 60 is referred to herein as a first command or a log-in command.

After the credits are displayed on meter 70, the player plays slot machine 12 in a conventional manner as described above. That is, the coin-in button (not shown) is depressed by the player to transfer the desired number of credits from credit meter 70 to coin-in meter 72. After so doing, the player presses spin button 53 to spin reels 48. Upon completion of the game, i.e., after the reels stop spinning, any jackpot payable according to a pay table internal to machine 12 is also applied to credit meter 70. Similarly, any bonuses, i.e., any payments to the player that result from awards not generated by the pay table in machine 12, as described in the '961 patent, are also applied to credit meter 70.

When the player concludes play on machine 12, he or she has two options for redeeming any balance remaining on credit meter 70. First, if cash-out button 74 is depressed while card 66 is received in card reader 60, the credits on meter 70 are transferred to the player account record contained in the RAM in MCI 50. Credit meter 60 then reads 0 credits, and the number of credits displayed on meter 70 when cash-out button 74 is depressed is associated with the player record in the RAM of MCI 50. As soon as this transfer occurs, display 58 indicates the amount transferred to the player. After the transfer to the RAM in MCI 50, the player record and associated credits is transferred via connection 22 over the network to the host computer. The term *host computer* as used herein may refer to a processor, a controller, or memory, which may be located anywhere, including multiple locations, on the network. In the present case, the host computer includes a dedicated storage area on player server 42. The information stored includes the amount, dollar amount, time that storage occurred and the machine number from which the credit was stored, all of which is associated with the identifying player record. Other data associated with the player record, such as the amounts wagered and won, is stored on accounting system 38 in accordance with prior art player tracking systems. Typically the player leaves the card in the card reader from beginning to end of play. This allows the player to be credited for points that can be redeemed for awards. It should be noted, however, that to effect the coinless transfer feature, the card need only be inserted when cash-out button 74 is depressed. In other words, the card need not necessarily be in the card reader during play -- the record can be fetched and the credits stored in the player account after all play is complete.

Alternatively, when the player concludes gaming on machine 12, he or she may choose to receive payment via hopper 78 at the machine. If so, the player withdraws card 66 from reader 60 before pressing cash-out button 74. Withdrawal of card 66 from card reader 60 is referred to herein as a second command or a log-out command. Because credits remain on credit meter 70, the player record in RAM of MCI 50 indicates 0 credits, which is stored to the host computer as described above with the player record. The player now depresses cash-out button 74 thus causing the machine to pay credits from meter 70 to hopper 78 in the usual fashion. Depressing cash-out button 74 is referred to herein as a request to redeem the balance stored on the credit meter.

Each slot machine includes conventional controls for setting a maximum amount payable from the hopper of the machine based upon the hoppers capacity and the casino's wishes. In addition, a maximum amount payable at hopper 78 may also be set by the casino

at configuration workstation 40 to prevent a player from cashing out credits over a predetermined maximum value. If either value – the value set at the machine or the value set at the workstation -- is exceeded, machine 12 locks up in the same fashion as if it had won a jackpot that exceeded the maximum amount payable from the machine hopper.

When a player elects to cash out by storing his or her balance with their player record on the host computer as described above, the player may use the card to transfer the credit to another slot machine on the network. To do so, the player moves to another machine, perhaps after taking a short break, and inserts his or her card 66 into the card reader, like card reader 60, associated with the new slot machine. The MCI, like MCI 50, at the new machine detects insertion of the card. The appropriate player record is called from the host computer, including the record stored on bonus server 44 having the amount of credits stored in the player's account. That record and the associated credits are stored initially in the RAM of MCI 50. The number of credits associated with the record is then transferred to the credit meter of the new machine without any further action on the part of the player. Play then continues as described above, including cashing out by either restoring the balance on the credit meter with his or her account on the host computer or withdrawing the card and cashing out to obtain payment via the machine hopper.

In another embodiment of the present invention, the coinless transfer feature may be implemented without requiring a player to deal with casino personnel. In this embodiment, the player account is anonymous, and is created by the player. In this embodiment, the casino provides an automated card dispenser, each card being coded with an anonymous player account that exists on the host computer. The player simply takes one of the cards from the dispenser and uses it to play as described above. The player has the same options to cash out, namely depressing cash-out button 74 with the card withdrawn to receive coin at the machine and depressing the cash-out button with the card inserted to apply the machine credits to his or her anonymous account in the same manner as described above for an account associated with an identified player. In the latter instance, when the player wishes to resume play, they merely insert the card into the card reader associated with the selected slot machine and credits are applied to the credit meter of the slot machine as described above. The player can also cash out by presenting the card to the cashier, also as described above. The anonymous coinless transfer system is advantageous in that casino personnel are not required to activate the coinless transfer feature.

In another aspect, the present invention limits the time between storing credits to a

player's account, whether anonymous or not, and accessing the account to resume play with credits in the account. In this aspect, the host computer initiates a timed count when the player withdraws his or her card from the card reader. The casino may select – at configuration workstation 40 – a maximum time, for example, 2 hours, that the player may access the account using a card reader. If this time is exceeded, the credits will not transfer from the account to the credit meter of the slot machine when the card is inserted. The player must therefore present the card to a casino cashier who can access the account using a card reader and reimburse the player with the total amount credited to his or her account. This feature reduces potential casino liability by not permitting card access to deposited credits for extended periods.

Modifications and variations such as would be apparent to a skilled addressee are deemed to be within the scope of the present invention.

Throughout the specification, unless the context requires otherwise, the word "comprise" or variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated integer or group of integers but not the exclusion of any other integer or group of integers.

The claims defining the invention are as follows:

1. A method for operating gaming devices interconnected by a computer network to a host computer comprising:

creating a player account accessible by the host computer;

providing access to the player account responsive to a first command initiated by a player at one gaming devices;

transmitting data representing the player account over the network to a local memory associated with the one gaming device;

transferring credit from the player account to said one gaming device;

permitting gaming device play; and

cashing out from the gaming device responsive to a further command initiated by said player at said one gaming device.

2. The method of claim 1 wherein creating a player account accessible by the host computer comprises:

providing a tracking card to the player;

storing a player record on the host computer;

receiving an initial cash deposit from the player; and

crediting the deposit to the player account.

3. The method of claim 2, wherein said gaming devices are in a casino and wherein creating a player account accessible by the host computer is performed at an automated card dispenser.

4. The method of claim 2, wherein said gaming devices are in a casino and wherein creating a player account accessible by the host computer is performed by an agent of the casino at a terminal connected to the network.

5. The method of any one of claims 1 to 4, wherein said first command comprises insertion of a player tracking card into a card reader associated with said one gaming device.

6. The method of any one of claims 1 to 5, wherein said further command comprises actuating a cash-out actuator at said one gaming device.

7. The method of any one of claims 1 to 6, wherein said player account is an anonymous player account.

8. The method of any one of claims 1 to 7, wherein said method further comprises:

measuring the time between each transaction on the player account; and

locking the player account when the time measured exceeds at least one established criterion.

9. A method for operating gaming devices interconnected by a computer network to a host computer that contains a plurality of player accounts accessible at the gaming devices, said method comprising:

transmitting data representing a player account over the network to a local memory associated with one of the gaming devices;

transferring any balance in the player account to a credit meter associated with the one gaming device responsive to a log-in command initiated by a player at said one gaming device;

storing any awards resulting from gaming device play on the credit meter;

detecting a player-initiated request to redeem the balance stored on the credit meter; and

transferring the balance on the credit meter to the player account.

10. The method of claim 9, wherein transferring the balance on the credit meter to the player account comprises transferring data from the credit meter to the player account in the local memory.

11. The method of claim 10, wherein said method further comprises transferring the player account data from the local memory to the host computer responsive to a log-out command initiated by a player at said one gaming device.

12. The method of any one of claims 9 to 11, wherein said method further comprises:

detecting a log-out command initiated by a player at said one gaming device;

transferring any balance in the player account to a second credit meter associated with a second one of said gaming devices responsive to a log-in command initiated by the player at the second gaming device; and

storing any awards resulting from play on said second gaming device on the second credit meter.

13. The method of claim 12, wherein said method further comprises:

initiating a timed count responsive to the log-out command; and

preventing transfer of the balance in the player account to the second credit meter if the timed count exceeds a predetermined maximum when the log-in command is initiated at said second gaming device.

14. The method of any one of claims 9 to 13, wherein said method further comprises:

detecting money paid by the player to the gaming device; and

applying the money paid to the credit meter of the gaming device.

15. The method of any one of claims 9 to 14, wherein transferring any balance in the player account to a credit meter associated with the one gaming device responsive to a log-in command initiated by a player at said one gaming device comprises transferring the entire balance in the player account to a credit meter associated with said one gaming device responsive to a log-in command initiated by a player at said one gaming device.

16. The method of any one of claims 11 to 15, wherein the log-in command comprises inserting a card into a card reader associated with said one gaming device and wherein the log-out command comprises withdrawing the card.

17. A method for paying credits on gaming devices interconnected by a computer network to a host computer that contains a plurality of player accounts accessible at said gaming devices, said method comprising:

transmitting data representing a player account over the network to a local memory associated with one of the gaming devices;

transferring any balance in the player account to a credit meter associated with the one gaming device responsive to a log-in command at said one gaming device;

storing any awards resulting from gaming device play on the credit meter;

detecting a log-out command at said one gaming device; and

paying the balance on the credit meter to the player via said one gaming device.

18. The method of claim 17, wherein said method further comprises preventing gaming device payment of the balance on the credit meter if the balance is above a predetermined maximum.

19. The method of claims 17 or 18, wherein the log-in command comprises inserting a card into a card reader associated with said one gaming device and wherein the log-out command comprises withdrawing the card.

20. A method for operating gaming devices interconnected by a computer network to a host computer substantially as hereinbefore described.

21. A method for operating gaming devices interconnected by a computer network to a host computer that contains a plurality of player accounts accessible at the gaming devices substantially as hereinbefore described.

22. A method for paying credits on gaming devices interconnected by a computer network to a host computer that contains a plurality of player accounts accessible at said gaming devices substantially as hereinbefore described.

Dated this Sixteenth day of April 2003.

Acres Gaming, Inc.
Applicant

Wray & Associates
Perth, Western Australia
Patent Attorneys for the Applicants

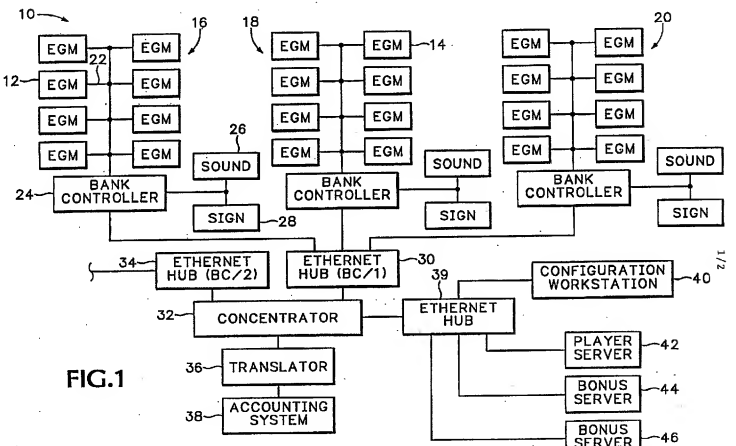


FIG.1

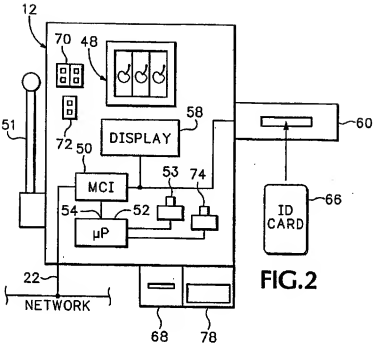

12
70
48
58
51
DISPLAY
60
72
50
MCI
53
74
66
54
52
ID
CARD
μP
22
NETWORK
68
78

FIG.2

PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 :
C12M 1/34, A61B 5/04
A61M 31/00, 1/34

A1

(11) International Publication Number: WO 91/16416

(43) International Publication Date: 31 October 1991 (31.10.91)

(21) International Application Number: PCT/US91/02911

(22) International Filing Date: 25 April 1991 (25.04.91)

(30) Priority data:
513,993 26 April 1990 (26.04.90) US

(71) Applicant: MARKWELL MEDICAL INSTITUTE, INC. [US/US]; P.O. Box 085173, Racine, WI 53408 (US).

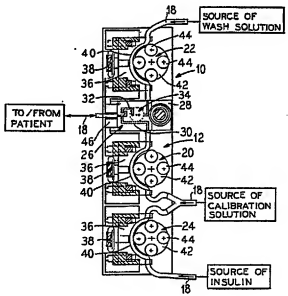
(72) Inventors: ZAMZOW, Kevin, L. ; 4922 Ascot Lane, #4, Madison, WI 53711 (US). SCHMIDT, Daniel, G. ; 6861 Stevenson Road, #2, Dane, WI 53429 (US). SHULTS, Mark, C. ; 2810 Gregory Street, Madison, WI 53711 (US). UPDIKE, Stuart, J. ; 1309 Whenona Drive, Madison, WI 53711 (US).

(74) Agents: HIERL, Michael, A. et al.; Olson & Hierl, 20 N. Wacker Drive, Suite 3000, Chicago, IL 60606 (US).

(81) Designated States: AT (European patent), AU, BE (European patent), CA, CH (European patent), DE (European patent), DK (European patent), ES (European patent), FR (European patent), GB (European patent), GR (European patent), IT (European patent), JP, LU (European patent), NL (European patent), SE (European patent).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: WEARABLE BLOOD GLUCOSE MONITOR



(57) Abstract

A wearable device (10) for continuously monitoring plasma glucose concentrations in samples of undiluted whole blood comprises an enzyme electrode assembly (34) and a plurality of interrelated pumps (20, 22, 24) which operate in a predetermined sequence to withdraw a blood sample from a patient for analysis and then return the entire volume of the blood sample to the patient. Methods are disclosed whereby glucose levels can be continuously determined in the plasma of undiluted whole blood sample without blood loss by the patient and whereby insulin can be infused in response to the determined glucose levels. Dilution of the blood sample caused by laminar flow during withdrawal of the blood sample is substantially eliminated.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	ES	Spain	MG	Madagascar
AU	Australia	FI	Finland	ML	Mali
BB	Barbados	FR	France	MN	Mongolia
BE	Belgium	GA	Gabon	MR	Mauritania
BF	Burkina Faso	GB	United Kingdom	MW	Malawi
BG	Bulgaria	GN	Guinea	NL	Netherlands
BJ	Benin	GR	Greece	NO	Norway
BR	Brazil	HU	Hungary	PL	Poland
CA	Canada	IT	Italy	RO	Romania
CF	Central African Republic	JP	Japan	SD	Sudan
CG	Congo	KP	Democratic People's Republic of Korea	SE	Sweden
CH	Switzerland			SN	Senegal
CI	Côte d'Ivoire	KR	Republic of Korea	SU	Soviet Union
CM	Cameroon	LI	Liechtenstein	TD	Chad
CS	Czechoslovakia	LK	Sri Lanka	TG	Togo
DE	Germany	LU	Luxembourg	US	United States of America
DK	Denmark	MC	Monaco		

WEARABLE BLOOD GLUCOSE MONITOR

Technical Field

The present invention generally relates to a system for determining the amount of a substance in a biological fluid and, in particular, to a wearable device and a method for continuously monitoring glucose concentrations in blood.

Background Of The Invention

Some medications must be administered at regular intervals to control a medical condition. Diabetes, for example, may be controlled by daily, or more frequent, injections of insulin to normalize blood glucose levels. It has been found in the treatment of certain conditions, including diabetes, that more effective treatment results from constant or repeated small doses of medication. This provides improved control of the medical condition and avoids the problems associated with under- and over-medication.

Systems have been developed in which a catheter is subcutaneously implanted in a patient, and a medication is supplied to the patient as desired through the catheter associated with a pumping apparatus. These systems, however, tend to be large and bulky and in some cases require a considerable power source.

For example, an apparatus was manufactured at one time under the trade name BIOSTATOR (by the Life Science Division of Miles Laboratories) for monitoring glucose levels and infusing insulin. The apparatus, however, was relatively complicated to operate and is no longer commercially available. In particular, the apparatus included a glucose sensor, a system for infusing insulin and a microprocessor which, through an appropriate algorithm, transformed values for glucose levels into an adequate administration of insulin (or glucose). A daily blood loss

of about 50 milliliters, and the non-portability of the apparatus along with the brief service life (less than about 50 hours) of the glucose sensor were significant disadvantages of the system.

Moreover, the apparatus subjected the blood sample to a continuous precision dilution before analysis, determined whole blood glucose rather than plasma glucose, required the use of a relatively large (18 gauge) cannula in a peripheral vein and weighed several hundred pounds. Furthermore, the accuracy of the apparatus was sensitive to changes in hematocrit.

Accordingly, there is need in the treatment of diabetes for a wearable and portable system having a reasonable cost that continuously monitors plasma glucose concentrations in undiluted whole blood samples and effectively administers insulin. The present invention satisfies that need.

Summary of the Invention

The present invention relates to a system for determining the amount of a substance in a biological fluid. In particular, the invention relates to a programmable device and a method for withdrawing a sample of whole blood from a patient, determining the concentration of glucose in the plasma of the blood sample without dilution of the sample and returning the entire blood sample to the patient. The patient experiences no loss of blood in the process. Means is also provided for calibrating and flushing the device along with means for treating the patient with a medication, such as insulin, in response to the results of the analysis.

The device is portable and lightweight, and can be constructed as a wearable unit for bedside and ambulatory use. In particular, the device comprises a housing adapted

for removable attachment to the patient. Means in communication with the housing is provided for withdrawing a blood sample from the patient for analysis and returning the entire blood sample to the patient after analysis. Sensing means connected to the withdrawing means determines the concentration of glucose in the plasma of the blood sample. First pump means, which is preferably bidirectional, has an inlet end operatively associated with a first channel of the sensing means and an outlet end in communication with a source of calibration solution. Second pump means, which is also preferably bidirectional, has an inlet end operatively associated with a second channel of the sensing means which is in communication with the first channel, and an outlet end in communication with a source of wash solution. In addition, means is provided for controlling the first and second pump means to withdraw and to return the blood sample in a predetermined sequence.

The withdrawing means includes a catheter for withdrawing the blood sample from the patient. The catheter remains inserted in a blood vessel of the patient for the withdrawal of blood at frequent intervals (about every two-five minutes) for continuous monitoring of the blood glucose level of the patient.

The calibration solution contains a predetermined amount of glucose and, along with the wash solution, includes an anti-coagulant (such as heparin or urokinase) in an amount sufficient to prevent the blood from clotting in the device but without significantly effecting the coagulating properties of the blood in vivo.

The sensing means comprises a flow cell which is disposable and can be releasably mounted on the housing. The flow cell includes a body portion having a first channel

in communication with a second channel. An enzyme electrode assembly is operatively associated with the second channel.

The juncture of the first and second channels provides an anti-convection barrier to prevent the blood sample or the calibration solution from entering the flow cell prematurely.

In particular, the cross-sectional area of the second channel is preferably less than the cross-sectional area of the first channel whereby the blood sample can flow through the first channel without flowing through the second channel. In an alternative embodiment, the second channel is substantially non-linear and is configured so that the blood sample can flow through the first channel without flowing through the second channel.

A third pump means can also be provided having an inlet end operatively associated with the first or the second channel of the sensing means and an outlet end in communication with a source of insulin. This pump means need not be bidirectional.

The device can also include means for detecting air (for example, an optical bubble detector) and for detecting hematocrit (for example, by electrical conductivity) in the device and thereupon providing a signal to the controlling means. The controlling means generally comprises electronic circuit means associated with the housing and operably associated with the enzyme electrode assembly for processing a signal from the electrodes of the enzyme electrode assembly. Display means operably associated with the electronic circuit means can also be provided for displaying a result.

The present invention also relates to a method of continuously determining the amount of glucose in the plasma of a sample of undiluted whole blood comprising the

steps of: withdrawing a blood sample from a patient utilizing catheter means including tubing in communication with sensing means which includes a first channel, a second channel in communication with the first channel and an enzyme electrode assembly operatively associated with the second channel; pumping the blood sample through the tubing and through the first channel of the sensing means using a first pump having a plurality of rollers which fully occlude the tubing as the rollers rotate; pumping the blood sample through the tubing and through the second channel of the sensing means using a second pump having a plurality of rollers which fully occlude the tubing as the rollers rotate; determining the concentration of glucose in the plasma of the blood sample as the blood sample flows through the enzyme electrode assembly; and infusing the entire blood sample into the patient after the amount of glucose in the blood sample has been determined.

The glucose determinations are made on an intermittent basis at frequent intervals to continuously monitor the blood glucose level of the patient.

Additional embodiments of the method include the step of pumping a calibration solution or a wash solution through the apparatus thereby flushing the apparatus and returning the entire blood sample to the patient; and the step of infusing a predetermined amount of insulin into the patient based on the amount of glucose in the blood sample.

The relatively compact device of the present invention is particularly well-suited for the controlled administration of insulin in managing the abnormal glucose metabolism which characterizes diabetes. Either a continuous slow injection or a series of small injections over a period of time can be provided to avoid the problems of over- and under-medication. Thus, the diabetic patient

can be provided with a lightweight wearable unit for monitoring blood glucose levels which includes a readily infusible source of insulin.

Numerous other advantages and features of the present invention will become readily apparent from the following claims, drawings and detailed description.

Brief Description of the Drawings

In the accompanying drawings, which comprise a portion of this disclosure:

FIGURE 1 is a perspective view of one embodiment of the present device being removably secured to the forearm of a patient;

FIGURE 2 is a plan view of the device of FIGURE 1;

FIGURES 3a-d are schematic diagrams of the analysis sequence of the device;

FIGURES 4a-b are schematic diagrams of the calibration sequence of the device; and

FIGURE 5 is a schematic view of an alternative embodiment of the device.

Description of the Preferred Embodiments

The device of this invention can be assembled and used in many different forms. This detailed description and the accompanying drawings disclose only specific forms which provide examples of the preferred embodiments. The particular shapes and the sizes of the components described herein are not essential to the invention unless otherwise indicated. Moreover, the invention is not intended to be limited to the embodiments illustrated.

In addition, the present device utilizes certain conventional analysis and control means, the type and operation of which will be apparent to those skilled in the art. The choice of materials is somewhat dependent on the particular application and other variables as will be

appreciated by those having an understanding of the operation and use of electronic instrumentation.

Referring to Figures 1 and 2, the present device 10 includes a main housing 12 which can be removably secured, for example, to the forearm of a patient to provide a wearable, portable analysis and infusion apparatus. In particular, the main housing 12 can be secured to support means comprising a cradle member 14 which wraps around the forearm and is removably secured thereto, as by Velcro straps 16.

The main housing 12 includes means for withdrawing and infusing a biological fluid, means for determining the amount of a substance in the biological fluid and means for treating the fluid. The following description relates to the determination of the concentration of glucose in the plasma of a sample of undiluted whole blood, and the treatment of the patient by infusing insulin to maintain desired blood glucose levels. However, it will be understood that the invention can be modified to determine the presence and the amount of other substances in biological fluids.

The withdrawing and infusing means include tubing 18 (with an associated catheter/needle) and pump means comprising a plurality of interrelated pumps 20, 22 and 24 which can be standard peristaltic or roller pumps of the type frequently used in blood treatment systems. One acceptable type of pump, which employs spring-loaded rollers, is Model SARA manufactured by SARNS of Ann Arbor, Michigan. The tubing 18 is preferably a flexible plastic material of the type ordinarily used in blood treatment systems which is compatible with the pump means. Such tubing is typically from about 0.01-0.06 inches in diameter depending on the application and flow rate demands.

Heparin-bonded tubing may be used for the end portions of the tubing to prevent clotting which otherwise might occur. In addition, urokinase can be used in controlled amounts to prevent fibrin formation in the tubing.

In a preferred embodiment, the withdrawing means, which comprises a catheter and associated tubing 18, withdraws a sample of undiluted whole blood from the patient for analysis and infuses the entire volume of the blood sample back into the patient so the patient does not experience any loss of blood.

Operatively associated with the withdrawing and infusing means is means for determining the amount of a substance in the biological fluid. Means including the pump 24 can also be provided for treating the fluid (for example, with insulin), although this is optional.

The means for determining the amount of a substance in a biological fluid comprises sensing means 26 in the form of a sensor and flow cell 28. The flow cell is preferably disposable in the form of a removable cartridge member; and comprises first and second channels 30 and 32, respectively, for the passage of a fluid and an enzyme electrode assembly 34 operatively associated with the second channel 32. The enzyme electrode assembly 34 is capable of sensing glucose accurately and precisely in the plasma of samples of undiluted whole blood.

In the illustrated embodiment, pumps 20, 22 and 24 are identical so the following description with regard to pump 20 relates to the construction of each pump. In particular, pump 20 comprises a platen member 36 which can be removably secured and accurately aligned to the main housing 12 by a convenient, easy-to-use latching mechanism 38. The platen member 36 includes an arcuate-shaped surface 40 on one side thereof. A portion of flexible tubing 18

through which the blood, a calibration solution or a wash solution can flow is positioned adjacent the arcuate-shaped surface 40 of the platen member 36. A rotatable member 42 mounted on the main housing 12 includes a plurality of equally-spaced rollers 44 (preferably four) and is operatively connected to a DC motor (not shown).

When the rotatable member 42 is rotated by the motor, the rollers 44 squeeze the tubing 18 against the arcuate-shaped surface 40 of the platen member 36 to collapse the tubing and thus displace the fluid in the tubing. The rollers 44 occlude the tubing fully so the pump, when stopped, blocks the flow of fluid in either direction. After a roller 44 has collapsed a portion of the tubing 18, the tubing re-expands to draw the appropriate fluid. The rotatable member 42 can rotate clockwise or counter-clockwise so the pump is bidirectional.

One problem that is common to all types of blood treatment systems is the need to prime the system before initial use. A common safety device in such systems is a bubble detector that monitors the blood or other fluids flowing through the tubing for the presence of air or other gases which could harm the patient.

In the present device, a detector 46 is positioned adjacent the flow cell 28 at the point where the blood from the patient enters the device. The detector ultrasonically or optically monitors the presence of an abnormal amount of air or foam in the fluid passing through the tubing 18, whether the fluid is the blood sample, the calibration solution, the wash solution or insulin. The detector 46, in association with the controlling means, responds to the occurrence of such an abnormal condition by deactivating the appropriate pump to prevent delivery of the air bubbles or foam to the patient. The detector 46 can

also monitor the passage of the blood sample to and from the device by sensing the passage of the interface between the blood sample and the wash or calibration solution.

The detector 46 can also measure the electrical conductance through a short segment of tubing and thus also monitor hematocrit which is known to those skilled in the art to be transducable by monitoring conductance. If the cannulated vein should become thrombosed or obstructed downstream, then the fluid withdrawn from the vein would show a decrease in hematocrit and signal that inadequate blood sampling is occurring.

The controlling means can include a central processor having both communication hardware and operational hardware. The communication hardware transmits information between the central processor and the individual wearing or operating the device. The communication hardware can include display means and an input device such as a keyboard having a plurality of input and output keys which determine the sequence and mode of operation of the device. The display means can include an electronic alphanumeric display which can both prompt the operator for input and display relevant operating parameters.

In a particularly preferred embodiment, a 200 microliter sample of venous blood is withdrawn from a patient (preferably from an arm vein) through a 22 gauge single lumen cannula or catheter with associated tubing 18. The blood is drawn through the tubing 18 and passes through the flow cell 28. A rate determination is completed in about 20 seconds or less, and the entire sample of whole blood is returned to the arm vein followed by a heparin-containing saline wash or calibration solution. No blood loss or significant systemic heparinization occurs. The

total cycle time is preferably about 1-5 minutes depending on the clinical situation.

Serial rate determinations of glucose are preferably made about every 1-5 minutes. After each glucose determination, the entire blood sample is flushed back into the patient with the heparin-containing wash solution. The wash solution comprises a physiologically acceptable saline solution without glucose and serves to determine the baseline zero glucose concentration signal which is needed for a drift-free rate determination. This is performed promptly to lessen the risk of blood clotting in the tubing after the analysis.

Moreover, in addition to providing a means for calibrating the device between readings, the calibration solution can also serve as a wash solution to flush the device and return the blood sample to the patient. The calibration solution comprises a saline solution including a predetermined concentration of glucose (for example, 200 mg/dl).

The method is linear to about 800 milligrams/deciliter glucose, is independent of hematocrit or physiological pO_2 and is free of interferences from blood constituents. The coefficient of variation is less than about 4 percent between calibrations. Moreover, the enzyme electrode assembly 34 has a service life of over one month. This wearable blood glucose analyzer is a significant improvement in the evaluation and treatment of diabetes.

An enzyme electrode assembly suitable for use in this invention is described in U.S. Patent No. 4,757,022 which issued to Shults et al. on July 12, 1988 and which is incorporated herein by reference. Other suitable enzyme electrode assemblies are disclosed in copending application

Serial No. 216,683, which was filed on July 7, 1988 and which is also incorporated herein by reference.

In particular, the enzyme electrode assembly comprises at least two electrodes carried by the main housing. A membrane associated with the second channel 32 of flow cell 28 is adapted to contact the electrodes when the flow cell is mounted on the housing. The membrane is a multilayered structure including layers formed of materials such as polyethylene, polyvinylchloride, tetrafluorethylene, polypropylene, cellophane, polyacrylamide, polymethyl methacrylate, silicone polymers, polycarbonate, cuprophane, collagen, polyurethanes and block copolymers thereof. The membrane prevents direct contact of the fluid sample with the electrodes, but permits selected substances of the fluid to pass through the membrane for electrochemical reaction with the electrodes. To ensure electrochemical reaction, the surface of the membrane layer nearest the electrode is preferably coated with a water-swellable film to maintain electrolyte at the electrode-membrane interface, and thereby improve the sensitivity of the measurement.

In a preferred embodiment, the membrane is a semi-permeable multilayered membrane having at least one layer formed of a nonporous block copolymer having hydrophobic segments and hydrophilic segments that limits the amount of a substance passing therethrough and a second layer including an enzyme that reacts with the substance to form a product.

In a more preferred embodiment, the electrode assembly comprises an electrode, a first (outer) layer of a block copolymer that limits the amount of a hydrophilic substance passing therethrough, a second (intermediate) layer of a block copolymer including an enzyme bound to the first layer and a third (inner) layer of a block copolymer

bound to the second layer and covering the surface of the electrode. The third layer is permeable to relatively low molecular weight substances, such as hydrogen peroxide, but restricts the passage of higher molecular weight substances.

It is generally accepted that a linear relationship between the concentration of the glucose analyte and the signal generated by the reaction product, H_2O_2, is desirable. Such a linear relationship exists for glucose at a concentration well below its Michaelis-Menten rate constant expressed quantitatively as K_m. This linearity, however, is outside the range of milligrams per deciliter that is generally of clinical interest.

The present enzyme electrode assembly avoids the problem of the non-linear relationship existing between the glucose analyte and the signal generated from the hydrogen peroxide reaction product within a clinically useful concentration range of from about 40 to about 400 milligrams glucose per deciliter. This is accomplished by (a) using a glucose oxidase enzyme electrode in which the enzyme immobilization technology used allows the electrode to measure plasma glucose in whole blood in the useful clinical range directly from an undiluted blood sample, and to do so independently of changes in hematocrit (hematocrit is well-recognized in the art as the volume percentage of red blood cells (RBC) in whole blood and indicates the ratio of RBC volume to plasma volume); (b) conducting the analysis so rapidly that the analytical result is not influenced by intracellular glucose (RBC glucose is always less than plasma glucose) and thus is indeed independent of hematocrit; and (c) using a multilayered, polyurethane-based polymer membrane matrix to entrap the enzyme which is (i) sufficiently hydrophobic to allow adequate transport of oxygen to be non-rate limiting with respect to oxygen, and

(ii) sufficiently hydrophilic to selectively allow the transport of water-soluble substances like glucose by preferential diffusion and (iii) sufficiently strong to stabilize the diffusion path length.

The operation of an enzyme electrode that is suitable for use in this invention is described in Updike et al., Diabetes Care, 11, 801-807 (1988) which is incorporated herein by reference. As demonstrated in that article, the glucose determination is independent of hematocrit. This feature was not previously demonstrated in any glucose detection method that utilizes a whole blood sample.

This linearity is achieved because the enzyme is immobilized in such a way that the rate-limiting step involves partitioning and diffusion of a substance such as glucose through the surrounding non-porous multilayered polymer membrane matrix. On the other hand, the porous membranes disclosed in the prior art use size exclusion filtration to control diffusion without achieving linearity in the physiological range.

The polyurethane-based membrane of the present enzyme electrode assembly not only selectively limits the amount of substance diffusing therethrough, it also provides an unusually strong and durable membrane. The strength and durability of the membrane allows the membrane to maintain a constant cross-sectional dimension for the diffusion path of glucose through the membrane to the electrode and thereby avoids calibration problems caused by variable or inconsistent path lengths seen with conventional porous membranes used in prior commercially available analyzers.

An additional problem associated with blood treatment and analysis systems relates to the accuracy of readings or determinations when a fluid flows through tubing, or a similar passage having a relatively small

cross-sectional area. In particular, when a Newtonian fluid passes through a tube, the portion of the fluid closest to the sidewall of the tube moves at a substantially slower rate than the portion of the fluid at the center portion of the tube (i.e., due to laminar flow). In fact, the maximum velocity of the fluid at the coaxial center of the tube is approximately twice the mean velocity of the fluid.

Thus, when a blood sample is withdrawn from the patient via the catheter and tubing 18 for passage through the flow cell 28 for analysis by the enzyme electrode assembly 34, the leading portion of the blood sample is diluted to some extent. This is because laminar flow causes the sample to partially mix with any fluid (e.g., a wash or calibration solution) that may remain in the tubing from a previous operational step involving the same patient.

In order to circumvent this unwanted and somewhat variable dilution, a volume of blood sample that is greater than that needed for the analysis must be withdrawn to completely flush the fluid (usually the wash or calibration solution) from the tubing 18 and the flow cell 34. As a result, the enzyme electrode assembly begins its analysis on a blood sample which has undergone an unwanted dilution. The precision of the readings obtained during use of such a system is substantially unaffected, but the accuracy of the readings can vary considerably.

Figures 3a-d are schematic diagrams of a representative analysis sequence using the present device. As shown in Figure 3a, blood is withdrawn from the patient through the single lumen catheter and associated flexible tubing 18 by a first roller pump 20. The rollers 44 of the pump fully occlude the flexible tubing 18 thereby allowing fluid to flow only when the pump is activated. At this point, heparin-containing wash solution is contained within

the tubing 18 associated with the second pump 22 and the enzyme electrode assembly 34.

Referring to Figure 3b, blood is drawn by the second pump 22 through the flow cell 28 immediately after the first pump 20 is stopped. Blood fills the tubing 18 associated with the first and second pumps and the flow cell, and the determination of the amount of glucose in the blood is performed.

As shown in Figure 3c, after the glucose determination is made, the blood is flushed or washed from the flow cell 28 and is infused into the patient along with a relatively small volume of the heparin-containing wash solution upon activation of the second pump 22. At this point, the catheter connected to the patient contains the wash solution as do the flow cell and the tubing associated with the second pump 22. However, the tubing positioned between the flow cell and the first pump 20 still contains a portion of the blood sample.

The step shown in Figure 3d is then performed to wash the device of the remaining portion of the blood sample. In particular, the first pump 20 is reactivated to infuse the remaining blood sample along with a relatively small volume of the heparin-containing calibration solution. In this manner, the entire volume of blood that was initially withdrawn from the patient is infused back to the patient. In a variation of this scheme, reinfusion of all blood may be done simultaneously by pumps 20 and 22.

Figures 4a-b are schematic diagrams of a representative calibration sequence using the device. Figure 4a is identical to Figure 3d because the last step of the analysis sequence is the same as the first step of the calibration sequence. In particular, the device has been washed free of the blood sample; the catheter and the tubing

18 between the patient and the first pump 20 contains the calibration solution; and the flow cell 28 along with the second pump 22 contain the wash solution.

As shown in Figure 4b, the enzyme electrode of the flow cell is then calibrated by activating the second pump 22 to draw the calibration solution into and through the flow cell.

Because the device can be supported on the forearm of the patient near the point where the blood sample is withdrawn, the hold-up volume within the tubing is minimized. This reduces the volume of blood necessary for the analysis. Moreover, the problem relating to the laminar flow and potential for dilution of the blood sample is reduced.

To further reduce the hold-up volume, the device, as shown in Figure 5, can embody a more comprehensive intravenous cannula that includes the sensor itself, and which thus eliminates the hold-up volume contained in tubing 18. The assembly comprises a cannula 48 having a distal or extracorporeal portion 50 which includes a housing 52 for supporting both the flow cell 28 and the enzyme electrode sensor 34. The cannula 48 preferably includes a plurality of openings 54 in the sidewall thereof to improve blood withdrawal characteristics. A flexible gasket 56 is provided to seal the electrical connections from the flow cell and housing. The housing 52 comprises a small, lightweight arm module which can be Luer-lok compatible with an associated catheter/needle assembly. A preamplifier can be supported by the housing which is operatively associated (preferably by a small umbilicus) with the source of calibration solution, the source of wash solution and the controlling means (which can be wearable or pole mounted).

This assembly avoids use of tubing 18 between the catheter/needle and the sensor.

The foregoing description is only illustrative of the principles of this invention. Since numerous modifications and changes will readily occur to those skilled in the art, it is not desired to limit the invention to the particular construction and mode of operation described herein. Accordingly, all suitable modifications and equivalents are intended to fall within the scope of this invention.

WHAT IS CLAIMED IS:

1. A wearable device suitable for continuously determining the plasma glucose concentration in a sample of undiluted whole blood from a patient comprising:

a) a housing adapted for removable attachment to the patient;

b) means in communication with the housing for withdrawing the blood sample from the patient for analysis and returning the entire blood sample to the patient after analysis;

c) means connected to the withdrawing means for sensing the concentration of glucose in the blood sample;

d) first pump means having an inlet end operatively associated with a first channel of the sensing means and an outlet end in communication with a source of calibration solution;

e) second pump means having an inlet end operatively associated with a second channel of the sensing means which is in communication with the first channel, and an outlet end in communication with a source of wash solution; and

f) means for controlling the first and second pump means to withdraw and to return the blood sample in a predetermined sequence.

2. The device according to claim 1 wherein the withdrawing means includes a catheter for withdrawing the blood sample from the patient, the catheter remaining inserted in a blood vessel of the patient for the withdrawal of blood at frequent intervals for continuous monitoring of the blood glucose level of the patient.

3. The device according to claim 1 wherein the calibration solution contains a predetermined amount of

glucose and an anti-coagulant in an amount sufficient to prevent the blood from clotting in the apparatus but without significantly effecting the coagulating properties of the blood in vivo.

4. The device according to claim 3 wherein the anti-coagulant is heparin.

5. The device according to claim 1 wherein the wash solution contains an anti-coagulant in an amount sufficient to prevent the blood from clotting in the apparatus but without significantly effecting the coagulating properties of the blood in vivo.

6. The device according to claim 5 wherein the anti-coagulant is heparin.

7. The device according to claim 1 wherein the cross-sectional area of the second channel is less than the cross-sectional area of the first channel whereby the blood sample can flow through the first channel without flowing through the second channel.

8. The device according to claim 1 wherein the second channel is substantially non-linear and is configured so that the blood sample can flow through the first channel without flowing through the second channel.

9. The device according to claim 1 wherein the sensing means comprises a flow cell including an enzyme electrode assembly, and the second channel is operatively associated with the enzyme electrode assembly for determining the concentration of glucose in the blood sample.

10. The device according to claim 1 including means for releasably mounting the sensing means on the housing.

11. The device according to claim 1 wherein the sensing means comprises a disposable cartridge.

12. The device according to claim 11 wherein the cartridge comprises a body portion for supporting an enzyme electrode assembly and means for removably mounting and aligning the cartridge on the electrodes associated with the housing.

13. The device according to claim 1 wherein the first and second pump means are bidirectional.

14. The device according to claim 1 including third pump means having an inlet end operatively associated with the first channel of the sensing means and an outlet end in communication with a source of insulin.

15. The device according to claim 1 including third pump means having an inlet end operatively associated with the second channel of the sensing means and an outlet end in communication with a source of insulin.

16. The device according to claim 1 including means for detecting air and changes in hematocrit in the device and thereupon providing a signal to the controlling means.

17. The device according to claim 1 wherein the controlling means includes electronic circuit means associated with the housing and operably associated with the enzyme electrode assembly for processing a signal from the electrodes of the enzyme electrode assembly.

18. The device according to claim 17 further including display means operably associated with the electronic circuit means for displaying a result.

19. The device according to claim 2 wherein the catheter has a distal portion which includes the flow cell and the enzyme electrode assembly.

20. A wearable device suitable for continuously determining the plasma glucose concentration in a sample of undiluted whole blood from a patient comprising:

a) a housing adapted for removable attachment to the patient;

b) means in communication with the housing for withdrawing the blood sample from the patient for analysis and returning the blood sample to the patient after analysis;

c) means connected to the withdrawing means for sensing the concentration of glucose in the blood sample, the sensing means comprising a first channel, a second channel in communication with the first channel and an enzyme electrode assembly operatively associated with the second channel for determining the presence of glucose;

d) first pump means having an inlet end operatively associated with the first channel of the sensing means and an outlet end in communication with a source of calibration solution;

e) second pump means having an inlet end operatively associated with the second channel of the sensing means which is in communication with the first channel, and an outlet end in communication with a source of wash solution; and

f) means for controlling the first and second pump means to withdraw and to return the blood sample in a predetermined sequence.

21. The device according to claim 20 wherein the withdrawing means includes a catheter for withdrawing the blood sample from the patient, the catheter remaining inserted in a blood vessel of the patient for the withdrawal of blood at frequent intervals for continuous monitoring of the blood glucose level of the patient.

22. The device according to claim 20 wherein the calibration solution contains a predetermined amount of glucose and an anti-coagulant in an amount sufficient to

prevent the blood from clotting in the apparatus but without significantly effecting the coagulating properties of the blood in vivo.

23. The device according to claim 22 wherein the anti-coagulant is heparin.

24. The device according to claim 20 wherein the wash solution contains an anti-coagulant in an amount sufficient to prevent the blood from clotting in the apparatus but without significantly effecting the coagulating properties of the blood in vivo.

25. The device according to claim 24 wherein the anti-coagulant in heparin.

26. The device according to claim 20 wherein the cross-sectional area of the second channel is less than the cross-sectional area of the first channel whereby the blood sample can flow through the first channel without flowing through the second channel.

27. The device according to claim 20 wherein the second channel is substantially non-linear and is configured so that the blood sample can flow through the first channel without flowing through the second channel.

28. The device according to claim 20 including means for releasably mounting the sensing means on the housing.

29. The device according to claim 20 wherein the sensing means comprises a removable cartridge.

30. The device according to claim 29 wherein the cartridge comprises a body portion for supporting an enzyme electrode assembly and means for removably mounting the cartridge on the housing.

31. The device according to claim 20 wherein the first and second pump means are bidirectional.

32. The device according to claim 20 wherein the entire volume of the blood sample is returned to the patient after analysis.

33. The device according to claim 20 including third pump means having an inlet end operatively associated with the first channel of the sensing means and an outlet end in communication with a source of insulin.

34. The device according to claim 20 including third pump means having an inlet end operatively associated with the second channel of the sensing means and an outlet end in communication with a source of insulin.

35. The device according to claim 20 including means for detecting air and changes in hematocrit in the device and thereupon providing a signal to the controlling means.

36. The device according to claim 20 wherein the controlling means includes electronic circuit means associated with the housing and operably associated with the enzyme electrode assembly for processing a signal from the electrodes of the enzyme electrode assembly.

37. The device according to claim 36 further including display means operably associated with the electronic circuit means for displaying a result.

38. The device according to claim 20 wherein the catheter has a distal portion which includes the flow cell and the enzyme electrode assembly.

39. A method of continuously determining the plasma glucose concentration in a sample of undiluted whole blood comprising the steps of:

a) withdrawing a blood sample from a patient utilizing catheter means including tubing in communication with sensing means which includes a first channel, a second channel in communication with the first

channel and an enzyme electrode assembly operatively associated with the second channel;

b) pumping the blood sample through the tubing and through the first channel of the sensing means using a first pump having a plurality of rollers which fully occlude the tubing as the rollers rotate;

c) pumping the blood sample through the tubing and through the second channel of the sensing means using a second pump having a plurality of rollers which fully occlude the tubing as the rollers rotate;

d) determining the concentration of glucose in the blood sample as the blood sample flows through the enzyme electrode assembly; and

e) infusing the entire blood sample into the patient after the concentration of glucose in the blood sample has been determined.

40. The method according to claim 39 wherein determinations are made on an intermittent basis at frequent intervals to continuously monitor the blood glucose level of the patient.

41. The method according to claim 39 including the step of pumping a calibration solution through the apparatus thereby flushing the apparatus and returning the entire blood sample to the patient.

42. The method according to claim 39 including the step of pumping a wash solution through the apparatus thereby flushing the apparatus and returning the entire blood sample to the patient.

43. The method according to claim 39 wherein cross-sectional area of the second channel is less than the cross-sectional area of the first channel whereby the blood sample can flow through the first channel without flowing through the second channel.

44. The method according to claim 39 wherein the second channel is substantially non-linear and is configured so that the blood sample can flow through the first channel without flowing through the second channel.

45. The method according to claim 39 further including the step of infusing a predetermined amount of insulin into the patient based on the concentration of glucose in the blood sample.

FIG. 1

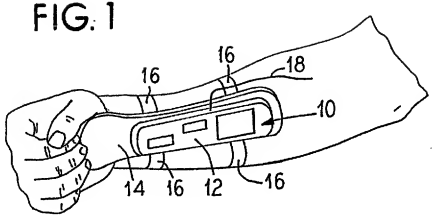

16
16
18
10
14
16
12
16

FIG. 2

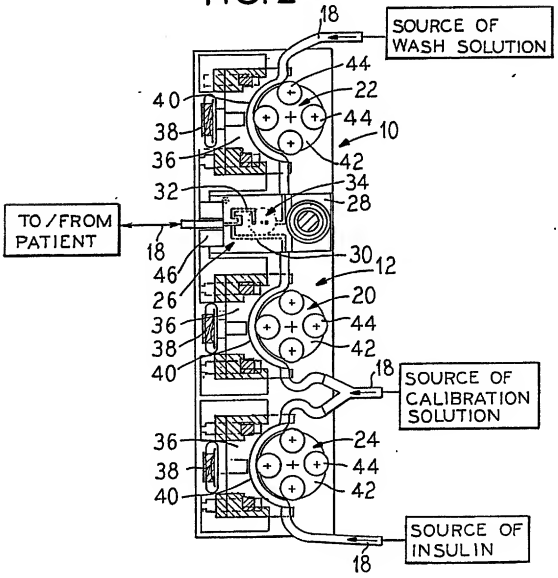

18
SOURCE OF WASH SOLUTION
44
40
22
44
38
10
36
42
34
32
28
TO/FROM PATIENT
18
30
12
46
26
20
36
44
38
42
40
18
SOURCE OF CALIBRATION SOLUTION
36
24
38
44
40
42
SOURCE OF INSULIN
18

FIG. 3a

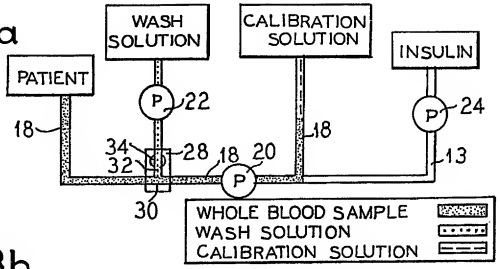


FIG. 3b

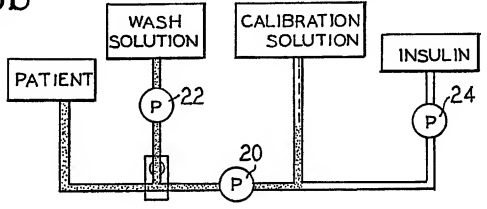


FIG. 3c

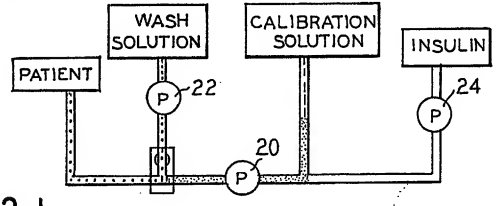


FIG. 3d

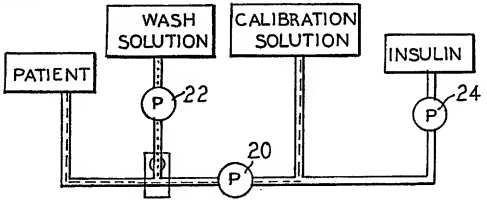


FIG. 4a

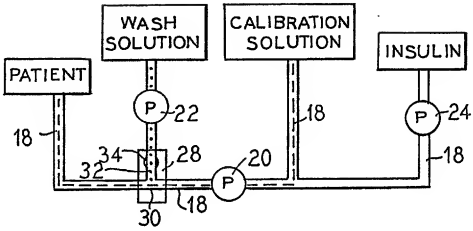
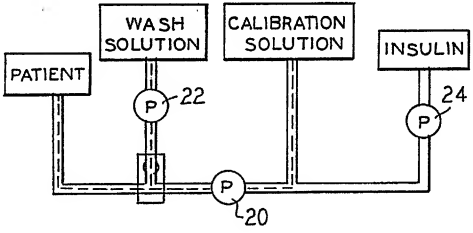
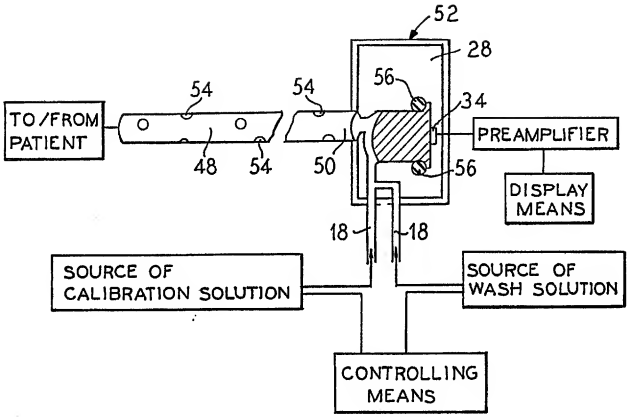

WASH SOLUTION
CALIBRATION SOLUTION
INSULIN
PATIENT
P
22
18
24
18
34
28
20
32
18
30

FIG. 4b


WASH SOLUTION
CALIBRATION SOLUTION
INSULIN
PATIENT
P
22
24
20


WHOLE BLOOD SAMPLE
WASH SOLUTION
CALIBRATION SOLUTION

FIG. 5


52
28
56
54
54
34
TO/FROM PATIENT
PREAMPLIFIER
48
54
50
56
DISPLAY MEANS
18
18
SOURCE OF CALIBRATION SOLUTION
SOURCE OF WASH SOLUTION
CONTROLLING MEANS

International Application No. PCT/US91/02911

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [6]

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC(5): C12M 1/34; A61B 5/04; A61M 31/00, 1/34

U.S. CL.: 435/291; 128/644, DIG 13; 604/67; 422/44

II. FIELDS SEARCHED

Minimum Documentation Searched [7]	
Classification System	Classification Symbols
U.S. CL.	422/82.01, 82.02, 82.03, 44; 435/291, 817; 128/635, 639, 644, DIG 12, DIG 13; 604/65, 66, 67

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [8]

APS Terms: Terms: Glucose, Insulin, Enzyme Electrode

III. DOCUMENTS CONSIDERED TO BE RELEVANT [9]

Category *	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No. [13]
Y	US,A 4,535,786 (KATER) 20 AUGUST 1985. SEE FIGURES 1-3. COLUMN 2, LINES 44-56.	1-8,13-15 39-44
Y	US,A. 4,240,438 (UPDIKE ET AL.) 23 DECEMBER 1980, SEE COLUMNS 3 AND 7.	1-8,13-15 45
Y	US.A. 4,757,022 (SHULTS ET AL.) 12 JULY 1988, SEE COLUMNS 3 AND 8.	9,17-18 20-27 31-34,36-37
Y	US.A, 4,786,394 (ENZER ET AL.) 22 NOVEMBER 1988. SEE FIGURE 9, ABSTRACT, COLUMN 8.	10-12,16 28-30,35
Y,P	US,A, 4,921,480 (SEALFON) 01 MAY 1990, SEE FIGURE 3, COLUMN 4.	16,35
Y	US.A, 4,016,864 (SIELAFF ET AL.) 12 APRIL 1977, SEE ABSTRACT.	19,38

* Special categories of cited documents: [10]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
17 July 1991	30 AUG 1991
International Searching Authority	Signature of Authorized Officer
ISA/US	Jan Ludlow

III. DOCUMENTS CONSIL ED TO BE RELEVANT (CONTINUED FROM THE SEC D SHEET)

Category *	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No
Y	THE LANCET, ISSUED 20 NOVEMBER 1982, M. SHICHIRI ET AL. "WEARABLE ARTIFICIAL ENDOCRINE PANCREAS WITH NEEDLE-TYPE GLUCOSE SENSOR" PAGE 1129-1131, SEE PAGE 1130.	1
A	J. LAB. CLIN. MED., VOLUME 93, NUMBER 4, ISSUED APRIL 1979, S.J. UPDIKE ET AL., "CONTINUOUS GLUCOSE MONITOR BASED ON AN IMMOBILIZED ENZYME ELECTRODE DETERCTOR," PAGES 518-527.	1-45
A	DIABETES CARE, VOLUME 11, NO. 10 ISSUED NOVEMBER-DECEMBER 1988, S.J. UPDIKE ET AL., "LABORATORY EVALUTION OF NEW REUSABLE BLOOD GLUCOSE SENSOR," PAGES 801-807.	9,17-18 20-27 31-34 36-37
A,P	US,A, 4,989,606 (GEHRICH ET AL.) 05 FEBRUARY 1991.	1-45
A	US,A, 4,221,567 (CLARK ET AL.) 09 SEPTEMBER 1980.	1-45
A	US,A,4,266,021 (NYLEN ET AL.) 05 MAY 1981.	1-45
A	US,A, 4,526,569 (BERNARD.) 02 JULY 1985.	1-45
A,P	US,A, 4,953,552 (DEMARZO) 04 SEPTEMBER 1990.	1-45
A,P	US,A, 4,974,592 (BRANCO) 04 DECEMBER 1990	1-45
A	US,A, 4,640,820 (COOPER) 03 FEBRUARY 1987	19
A	US,A, 4,633,878 (BOMBARDIERI) 06 JANUARY 1987.	1-45